



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/904,045	07/12/2001	John W. Butcher	20709	1941

210 7590 10/20/2003

MERCK AND CO INC
P O BOX 2000
RAHWAY, NJ 070650907

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
----------	--------------

1641

DATE MAILED: 10/20/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,045

Applicant(s)

BUTCHER ET AL.

Examiner

Mary (Molly) E. Ceperley

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-27 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1641

1) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2) Claims 5-27 are again rejected under 35 U.S.C. 103(a) as being unpatentable over **a)** Baldwin et al (U.S. Patent No. 5,633,247) taken in combination with each of **b)** Chadwick et al (Circulation Research, Vol. 72, No. 3, page 707 (1993)), Fiset et al (J. Mol. Cell Cardiol., Vol. 28, page 1085 (1996)), Geonzon et al (J. Mol. Cell Cardiol., Vol. 30, page 1691 (1998), or Duff et al (Circulation Research, Vol. 77, page 718 (1995) and with **c)** Dean et al (Synthesis and Applications of Isotopically Labeled Compounds, Paper 140 (1994)) for the reasons set forth in paragraph **6)** of the April 18, 2003 Office action.

Applicants' arguments filed July 21, 2003 have been fully considered but they are not persuasive. Applicants basically argue that the radiolabel ^{35}S "provides the high specific activity (>100 Ci/mmol) that is essential for an assay with adequate sensitivity" which would not be provided by either ^{125}I or ^3H radiolabels. However, Dean et al specifically compare the characteristics of all three types of labels and state at page 796:

"The high specific activity of sulfur-35 (maximum 1500 Ci/mmol), combined with a beta-emission of 0.167 MeV, a half-life of 87.4 days, and the potential to exist in a variety of oxidation states, make it an ideal alternative to tritiated and [^{125}I]iodinated compounds." (Emphasis added.)

Thus, Dean et al specifically suggest ^{35}S as a superior radiolabel for sulfonamides used as receptor binding probes (see the SUMMARY). The alleged improvement of using a ^{35}S radiolabel in a sulfonamide receptor binding probe is, in fact, an expected (obvious) result in view of the combined teachings of the prior art.

It is further noted that given the teaching of Dean et al that ^{35}S is a superior radiolabel for use in sulfonamide probe compounds, one skilled in the art would not in any way be motivated to introduce an unrelated/extraneous moiety such as an iodine radiolabel to the basic sulfonamide structure. The examiner agrees with the point made in the July 21, 2003 Remarks (page 4, last paragraph) that the introduction of an iodine atom might be expected to "severely compromise binding affinity at the targeted

\ Art Unit: 1641

protein, and adversely affect physiochemical properties". Similarly, Dean et al address the reason for using radiolabels other than tritium ("for cases in which specific activity beyond the upper limit of multiple tritium (25-100 Ci/mmol) are required") and specifically address the improvement accruing to the use of a ^{35}S label in sulfonamide compounds. As in the instant invention, the method of Dean et al "required high specific activity (>1000 Ci/mmol) sulfur-35 labeled sulfonamides for use as extremely sensitive receptor binding probes" (page 796, first paragraph).

3) THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

4) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (703) 308-4239. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556 or (703) 305-3592.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Application/Control Number: 09/904,045

Page 4

Art Unit: 1641

October 16, 2003


Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641